

ET



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,821	04/19/2001	Fatih M. Uckun	12152.77USD1	2823
23552	7590	08/10/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 08/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/838,821

Applicant(s)

UCKUN, FATIH M.

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-9,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-9,14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/19/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/22/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1656

## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
2. Applicant's response to the Office Action mailed May 23, 2003 on May 31, 2005, is acknowledged.
3. Claims 4-5 and 10-12 have been canceled. Claims 1-3, 6-9 and 14-15 are pending and are under examination.

### ***Specification Objection***

4. The disclosure is objected to because of the following informalities:

It is noted that applicant amended the specification to insert the continuity information, however, the information needs to be updated to report that the divisional application is now patented. It is suggested that the specification is amended to recite: "This application is a divisional of U.S. Application No. 09/345,815, filed June 30, 1999 which is now U.S. Patent No. 6,800,649 and claims priority to U.S. Provisional Application No. 60/091,150, filed June 30, 1998, which applications are incorporated herein by reference".

Correction is required.

***Information Disclosure Statement***

5. The information disclosure statement filed on March 22, 2005 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

***Withdrawn-Claim Objections***

6. Previous objection to Claims are withdrawn by virtue of submission of an amendment, which cancelled the claims.

***Withdrawn-Claim Rejections - 35 USC § 112***

7. Previous rejection to claims under 35 U.S.C. 112, second paragraph are withdrawn by virtue of submission of an amendment.

***Withdrawn- NonStatutory Double Patenting***

8. Previous rejection to claims under 35 U.S.C. 103, Obvious-type Double Patenting is withdrawn by virtue of submission of a Terminal Disclaimer.

***Maintained-Claim Rejections - 35 USC § 102***

Art Unit: 1656

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 and 14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ihle et al. (WO 95/03701, February 9, 1995).

Ihle et al. teach a method to inhibit the activity of Janus family of kinase including JAK-3 (abstract, page 11 and claims 1-9 of the reference). The method taught by Ihle et al. is performed *in vitro* (page 16) and uses a protein to inhibit the activity of JAK-3 (abstract and page 21, see claim 8 of the instant application). The reference further teaches that the method uses mammalian, human and avian cells (pages 15 and 32, see claim 1). Ihle et al. also teach a therapeutic wherein the inhibitor of JAK-3 is administered (page 35, claim 14). Therefore, the limitations of the claimed invention are met by the reference because Ihle et al. teach a method to inhibit the activity of JAK-3, which is necessary to inhibit c-jun activation as recited in claim 1 of the instant application (and the instant specification on page 8 discloses that an inhibitor of Janus family kinase 3 (JAK-3) can be used to inhibit c-jun expression).

### ***Maintained-Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1656

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 2-3, 8 and 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ihle et al. (WO 95/03701, February 9, 1995) in view of Narla et al. (Clinical Cancer Research, vol. 4, pages 1405-1414, June 1998) and Chae et al. (Cancer Research, vol. 53, pages 447-1151, February 1, 1993).

Ihle et al. teach a method to inhibit the activity of Janus family of kinase including JAK-3 (abstract, page 11 and claims 1-9 of the reference). The method taught by Ihle et al. is performed *in vitro* (page 16) and uses a protein to inhibit the activity of JAK-3 (abstract and page 21, see claim 8 of the instant application). The reference further teaches that the method uses mammalian, human and avian cells (pages 15 and 32, see claim 1). Ihle et al. also teach a therapeutic wherein the inhibitor of JAK-3 is administered (page 35, claim 14). The method of Ihle et al. inhibits the activity of JAK-3, which is necessary to inhibit c-jun activation as recited in claim 1 of the instant application (and the instant specification on page 8 discloses that an inhibitor of Janus family kinase 3 (JAK-3) can be used to inhibit c-jun expression).

In-so-far-as Ihle et al. do not explicitly teach radiation induced activation of c-jun (see claims 2 and 3), Narla et al. disclose the quinazoline derivative 4(4'-hydroxylphenyl)-amino-6,7-dimethoxyquinazoline as an inhibitor of the EGF-R tyrosine kinase (see page 1405, footnote 2 and 1409, col. 2, first paragraph) and Chae teach that protein tyrosine kinase activation precedes and perhaps mandates radiation induced activation of c-jun proto-oncogene expression in a human/mammalian cell (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole because Ihle et al. teach a method to inhibit the activity of JAK-3 which is necessary to inhibit c-jun activation as recited in claim 1 of the instant application (and the instant specification on page 8 discloses that an inhibitor of Janus family kinase 3 (JAK-3) can be used to inhibit c-jun expression) and Narla et al. teaches an inhibitor of protein tyrosine kinases which in turn inhibits c-jun and Chae teach that ionizing radiation increases the level of c-jun transcripts, thus activates c-jun. One of ordinary skill in the art would be motivated to combine the teachings of the references because it is known in the prior art that c-jun plays a role in cell proliferation; and the specification states that alterations of c-jun proto-oncogene expression can modulate the transcription of several growth-regulators affecting cell proliferation and differentiation (page 2). Moreover, the combined teachings of the reference indicates that c-jun expression is elevated in response to stimuli such as growth factors, cytokines and UV radiation and inhibited by quinazolines an inhibitor of JAK-3. Thus, the claimed invention is *prima facie* obvious.

### ***Response to Arguments***

11. The response filed on May 31, 2005 has been considered, however, is not fully persuasive. Regarding the rejection maintained under 35 U.S.C. 102, applicant on page 7 of the amendment state that the cited reference fails to disclose a method to inhibit activation of c-jun. It is also stated that the reference fails to disclose or suggest a role for JAK-3 in the activation of c-jun or that an inhibitor of JAK-3 would be useful to

Art Unit: 1656

inhibit the activation of the proto-oncogene, c-jun. This argument is not persuasive because the claimed method inhibits c-jun indirectly by inhibiting JAK-3. Cells are contacted with a JAK-3 inhibitor and the resulting effect is inhibition of c-jun activation. Although the method of the reference by Ihle et al. does not explicitly teach inhibition of c-jun, they disclose a method to inhibit JAK-3, which inherently will inhibit c-jun. Inhibition of c-jun activation is an inherent property of contacting cells with an inhibitor of JAK-3. Ihle et al. has a method to inhibit the activity of JAK-3 and a therapeutic wherein an inhibitor of JAK-3 is administered, the resulting effect must necessarily be inhibition of c-jun, thus, inherently an inhibition method for c-jun activation. "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing."; see *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963). Furthermore, in view of *In re Sussman*, 141 F. 2d 267, 60 U.S.P.Q. 538 (CCPA 1944), the claims are rejected under 35 U.S.C. 102 (b), "since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims." In the particular case, Applicant is claiming an invention employing the **same process steps** but the objective of the process is **alleged to be different**. Applicant is required to recite the missing steps to formulate the alleged differences in view of the above cited decision. Therefore, the rejection remains.

Regarding the rejection maintained under 35 U.S.C. 103, applicant on page 8 of the amendment state that the primary reference is cited as teaching a method to inhibit JAK-3 which fails to teach or suggest a method for inhibiting the proto-oncogene, c-jun, using an inhibitor of JAK-3. It is further stated that the secondary reference does not

Art Unit: 1656

cure the deficiencies of the primary reference. This argument is not persuasive because as stated above the primary reference, Ihle et al. remain relevant to the claimed invention. Additionally, the secondary reference by Narla et al. teach a quinazoline derivative which are recognized in the art as inhibitors of JAK-3 and Chae teach that ionizing radiation increases the level of c-jun transcripts, thus activates c-jun. Furthermore, claim 14 only requires that "c-jun activation is implicated". Thus, the claimed invention is prima facie obvious and the rejection remains.

It is noted that applicant filed a Terminal Disclaimer to address the obvious-type double patenting rejection. It is also noted that applicant on page 7 of the response state that "the examiner is requested to reconsider the necessity of a terminal disclaimer in light of amendments made to the claims". The patented claims and the instant claims are related as genus and species, thus the Terminal Disclaimer filed has been accepted and is necessary.

### ***Conclusion***

12. No claims are allowable.

13. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1656

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/838,821  
Art Unit: 1656

Page 10

Hope Robinson, MS

Patent Examiner

*[Handwritten signature]*  
8/2/05

*[Handwritten signature]*

KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER